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09/103,355      06/23/98      KUSHNER      P      23070-080510

020350      HM22/0410  
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EXAMINER

PAK, M

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

04/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/103,355**

Applicant(s)

**Kushner et al.**

Examiner

**Michael Pak**

Group Art Unit  
**1646**



☒ Responsive to communication(s) filed on Jan 19, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 14-28 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Group I, claim 1-13, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that examination of all three groups entails together entails no serious burden. This is not found persuasive because, as discussed in the last office action, classification of Group III is separate from group I and II. Furthermore, the preamble stated purpose of Group I and II are separate and distinct requiring separate search in the art for an agent which modulates transcription of Group II.

The requirement is still deemed proper and is therefore made final.

### *Claim Objections*

2. Claim 6 is objected to because of the following informalities. Appropriate correction is required.

Claim 6, line 3, recite "a an" which appears to be a grammatical error.

### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by

a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,723,291. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-13 of the present application encompasses the invention of claims 1-27 of U.S. Patent No. 5,723,291. It would have been obvious at the time of the invention to modify the method of claims 1-27 of U.S. Patent No. 5,723,291 which meets the limitations of claims 1-13 because the cells with the claimed limitations are taught by claims 1-27 of U.S. Patent No. 5,723,291 and can be used for comparison to detect responses.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing and ambiguous because claim 2 further comprises a second cell from the method of claim 1 but then the claim 3 limitation is directed to first and second cell being the same cell. It is not clear how the second cell can be the same cell in claim 3 if the claim 2 further comprises the second cell from the method of claim 1. Claim 3 is dependent from claim 2 and claim 2 is dependent from claim 1.

Claim 5 is confusing and ambiguous because claim 4 further comprises a second cell from the method of claim 1 but then the claim 5 limitation is directed to first and second cell being the same cell. It is not clear how the second cell can be the same cell in claim 5 if the claim 4 further comprises the second cell from the method of claim 1. Claim 5 is dependent from claim 4 and claim 4 is dependent from claim 1.

Claim 7 recites the limitation "said cognate receptor" in line 1. There is insufficient antecedent basis for this

limitation in the claim.

Claim 9 recites the limitation "said cognate receptor" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "said cognate receptor" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "said cognate receptor" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

Claims 1-13 preamble stated purpose "for screening a nuclear transcription factor ligand for the ability to modulate estrogen activation at an AP-1 site" is not fulfilled because there is no specific step where transcription factor ligand specifically modulate estrogen activation at an AP-1 site. Furthermore, there is no control experiment step which provides specificity to the method preamble stated purpose.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-5, 8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Kushner et al. ((AB); U.S. 5,723,291).

Kushner et al. teach a method with a cell or cells which express the claimed limitation components (columns 4-8, 10-12, and 17-20).

Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. The definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3.

10. Claims 1-5, 8, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by GAUB et al. ((AV); Cell, 1990).

GAUB et al. teach a method using the cell comprising estrogen receptor, ovalbumin element which is target for transactivation by c-fos and c-jun linked to CAT reporter (page 1271 and figure 6). Cells are contacted with TPA or forskolin and the receptor (HE0) and fos and jun and reporter activity measured (page 1271 and figure 6). Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. TPA and forskolin activates the cell thus are compounds which have AP-1 mediated estrogenic activity. Thus, claim 1 limitations are met. Claim 2 requires a second cell and figure 6 were performed with more than one cell in a cell culture which comprises the all the elements of the first cell which meet the limitations of claim 2. Claim 3 limitation is that the cells are the same which is met above. Claims 4 and 5 definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3.

11. Claims 1-5, 8 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. ((B); U.S. 5,639,592).



Evans et al. teach a method with a cell or cells which express the claimed limitation components (columns 3-7).

Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. The definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3.

12. Claims 1-2, 4, 8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfahl et al. ((A); U.S. 6,004,748).

Pfahl et al. teaches a method of detecting AP-1 interaction with cell containing estrogen receptors and as well as AP-1 promoter (columns 1-3 and 7-8).

Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. The definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Webb et al.(CB) and Kushner et al.((AD); WO 95/06754) are cumulative references with Kushner et al.((AB); U.S. 5,723,291), Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990).

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*

Michael D. Pak  
Primary Patent Examiner  
Art Unit 1646  
7 April 2000